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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,842	12/10/2001	Reena Rao	11378.36US01	1838
23552	7590	05/16/2005	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903				JIANG, SHAOJIA A
ART UNIT		PAPER NUMBER		
		1617		

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/014,842	RAO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 February 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-9 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) 11-19 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

This Office Action is in response to Applicant's amendment and response filed on February 7, 2005 wherein claims 1-9 have been amended; claim 10 is cancelled previously.

Currently, claims 1-9 and 11-19 are pending in this application.

It is noted that claims 11-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, of record in the previous Office Action dated February 4, 2004.

Claims 1-9 are examined on the merits herein.

Applicant's amendment that amends claim 6, filed February 7, 2005 with respect to the rejection made under 35 U.S.C. 112 first paragraph for lack of scope of enablement of record stated in the Office Action dated November 4, 2004 has been fully considered and is found persuasive to remove the rejection since the recitation "modulate" has been removed from the claim. Therefore, the said rejection is withdrawn.

The following is new rejection(s) necessitated by Applicant's amendment filed on February 7, 2005.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment with respect to amended claims herein has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for "about 45.5 mol% to about 46 mol% of omega-6 polyunsaturated fatty acids".

The original specification clearly discloses two specific points, or two species "45.5 mol%" and "46 mol%" (see page 9 line 10 and the last line of the table). The range now claimed "about 45.5 mol% to about 46 mol%" is considered to be the genus range of specific points within the genus range. The specification as originally filed does not provide support for any range of "about 45.5 mol% to about 46 mol% of omega-6 polyunsaturated fatty acids", nor does "about 45.5% mol".

The court held that "subgenus range was not supported by generic disclosure and specific example within the subgenus range"; See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971); the court also held that "a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads" (see *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972). See also MPEP 2163.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is

now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Kaimal et al. ("Modification of vegetable oils by lipase catalyzed interesterification," Journal of Oil Technologist 's Association of India, Jan-March 2-10, 1989, of record).

Kaimal et al. discloses the interesterification of coconut oil with safflower oil, by the catalyst, lipase, producing the interesterified coconut oil comprising linoleic acid (18:2), a known omega 6 polyunsaturated fatty acid, and lauric acid (12:0). Kaimal et al. also discloses that by interesterification of coconut oil with safflower, linoleic acid has been increased to 8.2% by weight in the interesterified coconut oil from 1.9% by weight in original coconut oil (see Tables 17-18 for example); lauric acid (12:0) has been reduced to 39.7% by weight in the interesterified coconut oil from 47.7% by weight in original coconut oil. Kaimal et al. further discloses that increasing the linoleic acid content in the coconut oil would yield a product of high stability and good nutritive value and good for patients under coronary care (see page 8).

The cited prior art does not expressly disclose the amount of linoleic acid (18:2), a known omega 6 polyunsaturated fatty acid in 45.5 mol% and lauric acid (12:0) in 17 mol%.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to prepare the interesterified coconut oil comprising linoleic acid (18:2), a known omega 6 polyunsaturated fatty acid in 45.5 mol% and lauric acid (12:0) in 17 mol%.

One having ordinary skill in the art at the time the invention was made would have been motivated to prepare the interesterified coconut oil comprising linoleic acid (18:2), a known omega 6 polyunsaturated fatty acid in 45.5 mol% and lauric acid (12:0) in 17 mol%, since the same method, lipase-interesterification of coconut oil with safflower, is known in the art according Kaimal et al. It is also known that linoleic acid has been increased to 8.2% by weight in the interesterified coconut oil from 1.9% by weight in original coconut oil, and lauric acid (12:0) has been reduced to 39.7% by weight in the interesterified coconut oil from 47.7% by weight in original coconut oil according Kaimal et al.

Moreover, the benefit for increasing the linoleic acid content in the coconut oil would be yielding a product of high stability and good nutritive value and good for patients under coronary care according to Kaimal et al. Thus, the teachings of Kaimal et al. has provided the motivation for the instant claimed invention.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Note that it has been well settled that recitation of an inherent property of a composition, e.g., the melting point, as discussed in the previous Office Action.

Applicant is further requested to note that it is well settled that "intended use" of a composition or product, e.g., "hypcholesterolemic and hypotriglyceridemic" in claims 2-4, will not further limit claims drawn to a composition or product. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Furthermore, it is noted that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). The product-by-process claim was rejected because the end product. See MPEP 2113.

Thus, even though product-by-process claims herein are limited by and defined by the process, the determination of patentability is based on the product itself. Since the end product, the structured lipids, is known in the art, the product-by-process claim was rejected because the end product.

Applicant's remarks filed on February 7, 2005 with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art. These remarks are believed to be adequately addressed by the obvious rejection presented above.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Art Unit 1617  
May 6, 2005